

## REMARKS/ARGUMENTS

### **Foreign Priority**

An English translation of Korean Patent Application KR20030078503 has been submitted with this Response.

The Examiner is requested to change the Priority Date of the Present Application to November 7, 2003, the filing date of Korean Patent Application KR20030078503, of which it seeks Priority.

### **Claims**

#### 35 USC § 112 ¶ 1 Rejections

The Office Action rejected Claims 2 - 13 under 35 USC § 112 ¶ 1 as failing to comply with the enablement requirement. The Office Action states “the specification, while being enabling for treating ischemic brain disease/stroke, does not reasonably provide enablement for the treatment and prevention of any and all brain diseases caused by degeneration.”

Applicants have amended Claims 4 and 5 to read “ischemic brain disease”. The Examiner is requested to remove the 35 USC § 112 ¶ 1 Rejection of Claims 2 - 13. In light of the foregoing amendments to the claims, the Examiner is respectfully requested to allow Claims 2 - 13.

#### 35 USC § 112 ¶ 2 Rejections

The Office Action rejected Claim 6 under 35 USC § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action stated “Claim 6 recites the phrase “sitologically acceptable additive” in lines 1-2. It is not clear what this term means. Is this a misspelling of ‘cytologically’ or does this term have another meaning?”

The term “sitologically” is spelled correctly. The root “sito” is from the Greek and means “food”. Therefore, the phrase “sitologically acceptable additive” means “any substance the intended use which results or may reasonably be expected to result-directly or indirectly-in its becoming a component or otherwise affecting the characteristics of any food` for example,

thickening agent, maturing agent, bleaching agent, sequesterants, humectant, anticaking agent, clarifying agents, curing agent, emulsifier, stabilizer, thickener, bases and acid, foaming agents, nutrients, coloring agent, flavoring agent, sweetener, preservative agent, antioxidant, etc.”

The Examiner is requested to remove the 35 USC § 112 ¶ 2 Rejection of Claim 6. In light of the foregoing argument, the Examiner is respectfully requested to allow Claim 6.

35 USC § 102(b) Rejection of Claims 2 - 3, 5 - 7, and 9 – 13.

The Office Action rejected Claims 2 - 3, 5 - 7, and 9 - 13 under 35 U.S.C. 102(b) as being anticipated by Sekimoto (JP 11302142). The Office Action stated “Sekimoto teaches a food composition which comprises a grape seed extract (see e.g. claim 2).”

Independent Claim 2 has been amended to claim the grape seed extract as a “product by process”, and as such, it is the Product that is being claimed. MPEP 2113 states “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.”

The process described in Sekimoto ‘142 has major and significant differences from the process in Claim 2, and the end-product obtained by the Sekimoto ‘142 process is not the same product obtained by the process in Claim 2.

The product in Claim 2 is an extract. An extract is a complex combination of chemicals (varying ratios of individual chemicals combined with the presence or absence of individual chemicals) that is determined by the precise method of extraction. The term “extract” does not describe a precise combination of chemicals unless it is connected with a method describing the precise process to obtain that extract. Various treatments, such as, temperature and duration, solvent used at a particular stage in the process, or solvent fraction in which the extract is retained, will determine the final milieu of chemicals, minerals, proteins, and peptides; concentration of each item; ratio between each item, and activity of biological factors, which will be specific for that process.

In general, the process under discussion is used to isolate complex extracts from a biological source (plants). The isolation is accomplished by using a chemical’s affinity for various solvents, and partitioning and isolating the desired chemical by a series of steps that causes a chemical to have a greater affinity for one of two solvents or between a substrate and a

solvent. Therefore, the order of the steps and solvent used at each step is very important to obtaining a desired complex extract.

For example; if step A is a non-polar solvent and step B is a polar solvent, then a process that subjects a substrate to Step A then Step B will produce a different product than a process that subjects a substrate to Step B then step A. The first process ( $A \rightarrow B$ ) will obtain non-polar chemicals that have a greater affinity to a polar solvent, whereas the second process ( $B \rightarrow A$ ) will obtain polar chemicals that have a greater affinity to a non-polar solvent.

Sekimoto '142 discloses a food constituent to treat oral diseases without making any detailed disclosure concerning the composition. A careful reading of the English translation of Sekimoto '142 shows that it only discloses using a single solution step, which can be a single solvent or a combination of two or more [paragraph 29]. Purification of this extract is disclosed as using a "countercurrent distribution method" or "liquid chromatography" [paragraph 31]. Additionally, Sekimoto '142 discloses in paragraph 33 that the methods in JP06-31208B, JP63-162685A, JP03-200781A, and JP02-48593A can be used for extraction. A review of the English abstracts of JP63-162685A, JP03-200781A, and JP02-48593A (an English abstract of JP06-31208B was unavailable) show none of these methods disclose the process claimed in Claim 2.

JP63-162685A [Appendix I] discloses "extraction of various vegetables with an aqueous medium is adsorbed to a PS resin" and "the adsorbed component is eluted with a polar solvent"

P03-200781A [Appendix II] discloses "grape pomaces or seeds are brought into contact with water, preferably at  $<70^{\circ}\text{C}$  .... and then extracted with water at  $\geq 70^{\circ}\text{C}$ ."

JP02-48593A [Appendix III] discloses "plant extract obtd. by a well known method is treated by water deposition, it is treated for ultrafiltration with a membrane with a cutoff of 1,000-100,000 to remove high mol.wt. substance" and then "a "membrane with a cutoff of smaller than 3,000" is used to obtain the desired fraction.

Sekimoto '142, nor any of the cited "well-known approaches", disclose a process of extraction comprising an initial alkaline solvent extraction, collecting the supernatant and acidifying the solution to an acidic solution, collecting the precipitate and suspending in an alcohol solvent, mixing and collecting the supernatant, adding a non-polar solvent, mixing and collecting the supernatant, and lyophilizing the non-polar solvent to obtain a dried grape seed extract.

Therefore, Sekimoto '142 does not disclose each and every step in Claim 2. The final product extract disclosed in the present application cannot be the same as the composition disclosed in Sekimoto '142 due to the multiple differences in the order of the individual steps and the specific parameters at each step. These differences show that Sekimoto '142 neither anticipates nor makes obvious the composition in Claim 2.

Claims 2, 5, 9 and 10 have been amended to be Product by Process claims. Claims 3, 7, 8 and 11-13 are Canceled. Claim 14 – 16 are New and dependent from Claim 2. .

The Examiner is requested to remove Sekimoto '142 as a 102(b) Prior Art reference. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 2, 5, 9, 10, and 14-16.

#### 35 USC § 102(a) Rejection of Claims 1 - 8 and 11 - 13

The Office Action rejected Claims 1-8 and 11-13 under 35 U.S.C. 102(a) as being anticipated by Kim et al. (KR20040052398). The Office Action stated “Kim et al. teaches a method of preparing a grape seed extract.”

An English translation of priority document Korean Patent Application KR20030078503 has been submitted with this Response. Therefore, the Priority Date of the Present Application is November 7, 2003, the filing date of Korean Patent Application KR20030078503, of which it seeks Priority.

Kim et al. (KR20040052398) has a publication date of June 26, 2004, which is after the priority date of the Present Application, and therefore is not Prior Art.

The Examiner is requested to remove Kim et al. (KR20040052398) as a 102(a) Prior Art reference. In light of the foregoing arguments to the claims, the Examiner is respectfully requested to allow Claims 1 - 8 and 11 - 13.

#### 35 USC § 103(a) Rejection of Claims 2, 4, and 7 - 8

The Office Action rejected Claims 2, 4, and 7 - 8 under 35 U.S.C. 103(a) as being obvious over Sekimoto (JP 11302142).

Independent Claim 2 has been amended to a Product by Process claim and Claim 4 depends from Claim 2. Claims 7 and 8 have been Canceled.

The Examiner is requested to remove Sekimoto '142 as a 103(a) Prior Art reference. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 2, 4, and 7 – 8.

Remarks

Claims 1 – 26 are pending. Claim 1, 2, 4 - 6, 9 and 10 are Currently amended. Claims 2, 7 – 8, and 11 – 13 are Canceled. Claims 14 - 26 are New.

Applicant respectfully requests the entrance of the amendments. No New Matter was entered with these amendments.

No fees are believed due; however, the Commissioner is authorized to charge any additional fees now and in the future which may be due, including any fees for additional extension of time, or credit overpayment to credit card information.

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